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EXAMINER

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ART UNIT	PAPER NUMBER
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1619  
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**



### DETAILED ACTION

Claims 1-20 are pending. Claims 1-12 are drawn to a composition. Claims 13-15 are drawn to a cosmetic or pharmaceutical formulation. Claims 16-18 are drawn to a method for improving or maintaining a healthy skin barrier. Claims 19-20 are drawn to a method of treating or preventing damage to the skin.

### *Specification*

1. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper (see page 2, second full paragraph). Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 12, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 12 and 20 are rejected due to the phrase "white birch". It is not clear what is meant by the phrase. The rejection can be overcome by the addition of the phrase "bark extract".
5. Claim 18 is rejected for being confusing. Claim 18 is drawn to "the method of claim 1" while claim 1 is drawn to a composition.
6. Claim 20 is rejected for being confusing due to the phrase "of the of the".
7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As held by *ex parte Forman* (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (8 USPQ 2d 1400, CAFC), there are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation.

Amount of guidance present: The specification fails to provide any guidance for preventing damage to the skin.

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Absence of working example: The specification fails to provide any working examples relating to the prevention of damage to the skin in the instantly claimed method.

Nature of invention: The nature of the invention is a method of using a composition of cholesterol sulfate and an amino sugar. However, the claim of preventing damage to the skin does not seem to fit in with the nature of the invention. It is not clear how the composition can be used in the instantly claimed method.

State of the prior art: The state of the prior art for preventing damage to the skin is not well understood. It is not clear that modifying the skin barrier function can prevent skin damage rather than treat damaged skin.

Relative skill of those in the art: Those in the art would not be able to practice the instantly claimed method with the composition in the claim, since this would amount to undue experimentation to test which possible combinations and formulations are useful.

Unpredictability in the art: Given the diversity of ways to damage the skin and the general lack of use of preventatives in skin care, it would be very unpredictable to use the combination of cholesterol sulfate and an amino sugar in the instant claimed methods.

Breadth of claims: The claims are broad, wherein all types of skin damage are prevented.

One way to overcome the rejection is by removal of the phrase "or preventing" in the claim.

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***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sebag et al (US Pat. 5,411,742). Sebag discloses compositions comprising derivatives of salicylic acid and cholesterol sulfate (see col. 3, lines 1-33; lines 1-col. 6, lines 15-23; and col. 16, lines 15-66). Salicylic acid is a known exfoliant.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-4, 6-10 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Sebag et al (US Pat. 5,411,742) in view of Subbiah (US Pat. 6,150,381).

13. Sebag teaches topical compositions comprising salicylic acid derivatives and cholesterol sulfate (see col. 3, lines 1-56; col. 7, lines 15-50; and col. 16, lines 15-66). Salicylic acid is an exfoliant. The compositions also contain cholesterol and linoleic acid (see col. 17, lines 5-25). The treatment of acne is taught. The reference lacks sclareolide.

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14. Subbiah teaches the use of sclareolide in topical formulations, particularly for acne (see abstract). Sclareolide is taught in combination with other ingredients (see col. 5, line 6 through col. 7, line 12). Subbiah teaches that sclareolide has antimicrobial activity that is useful in the treatment of acne (see col. 4, lines 45-65).

15. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Sebag by the addition of sclareolide for the expectation of improved antimicrobial activity of the composition as taught by Subbiah.

16. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al (US Pat. 5,650,166) in view of Subbiah (US Pat. 6,150,381).

17. Ribier teaches moisturizing compositions for the treatment of surface and deep layers of the skin. The compositions are comprised of dispersions of lipid vesicles containing active ingredients. Ribier teaches the use of cholesterol sulfate as a component of the lipid membrane of the vesicles (see col. 3, line 57 through col. 4, line 2). Ribier further teaches the use of sugars as the active ingredients, including N-acetylglucosamine (see col. 5, lines 59-67). Fatty acids, including linoleic acid (see col. 6, lines 44-46). Cholesterol is also taught as an active ingredient (see col. 6, lines 47-49). Ribier further teaches the use of plant extracts (see col. 7, lines 5-8). Treatment of the skin with respect to moisturization and loss of moisture to the environment are taught (see col. 1, line 7 through col. 2, line 30). It is the position of the examiner that a

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method to moisturize the skin with the composition as taught by Ribier inherently improves the healthy skin barrier. The reference lacks sclareolide.


18. Subbiah teaches the use of sclareolide in topical formulations, particularly for acne (see abstract). Sclareolide is taught in combination with other ingredients (see col. 5, line 6 through col. 7, line 12). Subbiah teaches that sclareolide has antimicrobial activity that is useful in the treatment of acne (see col. 4, lines 45-65).


19. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the compositions and methods as taught by Ribier by the inclusion of sclareolide for the expectation of antimicrobial properties as taught by Subbiah.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 8:30 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

  
Michael A. Willis, Ph.D.  
Patent Examiner  
July 2, 2001

  
Michael Hartley  
Primary Examiner  
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